IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

SHIRLEY J. BRINKLEY Plaintiff, v. PFIZER, INC., WYETH, LLC f/k/a WYETH, INC., SCHWARZ PHARMA, INC., and PLIVA, INC. f/k/a SIDMAK LABORATORIES, INC. Defendants.	)	Case No._____ JURY TRIAL DEMANDED

COMPLAINT

COMES NOW, Plaintiff Shirley J. Brinkley and for her causes of action against Defendants Pfizer, Inc., Wyeth, LLC f/k/a Wyeth, Inc., Schwarz Pharma, Inc., and Pliva, Inc. f/k/a Sidmak Laboratories, Inc. alleges as follows:

PARTIES

1. Plaintiff Shirley J. Brinkley (hereinafter referred to as "Plaintiff") is an individual who resides at 3917 NW Chapman Drive, Blue Springs, Missouri 64015, in Jackson County.

2. Defendant Pfizer, Inc. (hereinafter referred to as "Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd St., New York, New York 10017. Upon information and belief, Pfizer has merged with and/or acquired Co-Defendant Wyeth, LLC. Prior to said merger and/or acquisition, Wyeth, LLC was known as Wyeth, Inc. References in this Complaint to Pfizer include Pfizer individually

and, collectively, all divisions and/or subsidiaries, as well as successor-in-interest to Wyeth, LLC, Wyeth, Inc., A.H. Robins, Inc., American Home Products Corporation, and ESI Lederle, Inc. Pfizer may be served with process through its registered agent, CT Corporation System, 120 South Central Ave., Clayton, Missouri 63105.

3. Defendant Wyeth, LLC f/k/a Wyeth, Inc. (hereinafter referred to as "Wyeth") is a Delaware limited liability company with its principal place of business located at 5 Giralda Farms, Madison, New Jersey 07940. References to "Wyeth" include Wyeth LLC f/k/a Wyeth, Inc., individually, and collectively all divisions and/or subsidiaries, as well as successor-in-interest to A.H. Robins, Inc., American Home Products Corporation, and ESI Lederle, Inc.

4. Wyeth manufactures and distributes a generic form of Reglan® (metoclopramide) through its ownership of ESI Lederle, Inc. (hereinafter referred to as "ESI"), a former subsidiary which merged into Wyeth.

5. At all times material hereto, Wyeth was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor-in-interest, or other related entities, Reglan®, metoclopramide, and/or metoclopramide HCl in the State of Missouri and in interstate commerce. Wyeth may be served with process through its registered agent, CT Corporation System, 120 South Central Ave., Clayton, Missouri 63015.

6. Defendant Schwarz Pharma, Inc. (hereinafter referred to as "Schwarz") is a Delaware corporation with its principal place of business located at 6140 W Executive Dr., Mequon, Wisconsin 53092.

7. Defendant Schwarz, one of its predecessors in interest, and/or one of its

families of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan®, metoclopramide and/or metoclopramide HCl in the State of Missouri and in interstate commerce. Schwarz may be served with process through its registered agent, CSC Entity Services, LLC, 2711 Centerville Road, Wilmington, Delaware 19808.

8. Defendant Pliva, Inc. f/k/a Sidmak Laboratories, Inc. (hereinafter referred to as "Pliva") is a New Jersey corporation with its principal place of business located at 72 Eagle Rock Avenue, East Hanover, New Jersey 07936. On or about July 2002, Sidmak Laboratories, Inc. ("Sidmak") was acquired by Pliva, d.d., a Croatian corporation with its principal place of business located in Zagreb, Croatia. As a result, Sidmak's name was changed to Pliva, Inc. ("Pliva"). Consequently, and upon information and belief, Pliva is the successor-in-interest to Sidmak. Furthermore, upon information and belief, Pliva is also the successor-in-interest to a legal entity known as Pliva USA, Inc. ("Pliva USA"). At relevant times, Pliva and Pliva USA, Inc. were wholly-owned subsidiaries of Pliva, d.d. At relevant times, Pliva, d.d. was a wholly-owned subsidiary and/or division of Barr Pharmaceuticals, Inc. ("Barr"), which was a Delaware corporation with its corporate headquarters located in New Jersey. At relevant times, Pliva and Pliva USA were wholly-owned subsidiaries of Barr. On or about February of 2009, Barr was acquired by Teva Pharmaceutical Industries, Limited. ("Teva"). Teva is a corporation organized, existing, and doing business under the laws of the State of Israel, with its corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131. Pursuant to Teva's acquisition of Barr, Pliva is now a wholly

owned subsidiary of Teva. Unless stated otherwise, all references in this Complaint to "Pliva" include Pliva, Inc., Pliva USA, Inc., and Sidmak Laboratories, Inc.

9. At all times relevant hereto, Pliva was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor-in-interest, or other related entities, metoclopramide and/or metoclopramide HCl in the State of Missouri and in interstate commerce. Pliva may be served with process through its registered agent: Corporate Creations Network, 811 Church Road, #105, Cherry Hill, New Jersey 08002.

10 At all times relevant hereto, Defendants were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

11. At all times relevant hereto, Defendants were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising the pharmaceutical drugs known as Reglan®, metoclopramide, and/or metoclopramide HCl (hereinafter referred to as "Reglan/metoclopramide") in the State of Missouri and in interstate commerce.

VENUE AND JURISDICTION

12. This Court has diversity jurisdiction over this matter pursuant to 28 U.S.C. §1332 as there is complete diversity of citizenship between plaintiff and defendants and the amount in controversy exceeds $75,000, excluding costs and interest.

13. Venue is proper pursuant to 28 U.S.C. § 1391(a) because Plaintiff resides in this Judicial District and a substantial part of the events giving rise to the claims at issue arose in this District.

FACTS COMMON TO ALL COUNTS

14. At all times relevant, Plaintiff has been a resident of the State of Missouri.

15. On or about June 1992, Dr. Burnell Landers, Plaintiff's physician, prescribed Reglan/metoclopramide to Plaintiff to treat the motility of her stomach.

16. Plaintiff was prescribed and ingested the drug Reglan/metoclopramide consistently from on or about February 2002 until on or about April 2007.

17. Upon information and belief, Defendants researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged and/or advertised the Reglan/metoclopramide which was ingested by Plaintiff.

18. Plaintiff developed tardive dyskinesia and/or other neurological injuries after ingesting Reglan/metoclopramide.

19. Plaintiff brings this action for the purpose of recovering damages for the personal injuries she has suffered as a result of being prescribed and ingesting Reglan/metoclopramide.

20. Plaintiff was prescribed Reglan/metoclopramide on or about February 2002 in order to treat gastroesophageal reflux disease ("GERD").

21. The active ingredient of Reglan/metoclopramide is "metoclopramide," which is a dopamine antagonist.

22. Upon information and belief, the physician(s) who prescribed Reglan/

metoclopramide to Plaintiff on a long-term basis, from February 2002 through April 2007, relied upon information published in the package inserts and/or the Physicians' Desk Reference (hereinafter referred to as "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter referred to as "RLD") and/or the New Drug Application Holder (hereinafter referred to as "NDA Holder").

23. Plaintiff ingested the pharmaceutical drugs Reglan/metoclopramide as prescribed.

24. Plaintiff used the pharmaceutical drugs Reglan/metoclopramide without substantial change in the condition of the drugs between the time of design and manufacture of the drugs and the time Plaintiff used the drugs as directed.

25. Plaintiff's long-term ingestion of Reglan/metoclopramide directly and proximately caused her to develop tardive dyskinesia.

26. Plaintiff was not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR, RLD, or by the NDA Holders.

27. Upon information and belief, Plaintiff's Reglan/metoclopramide was discontinued on or about April 2007 because she exhibited movement abnormalities consistent with tardive dyskinesia.

28. Plaintiff was diagnosed with tardive dyskinesia secondary to Reglan/metoclopramide usage on or about April 2007.

29. Plaintiff's use of Reglan/metoclopramide, as prescribed, resulted in overexposure to the drugs which have caused her to suffer serious, permanent and disabling injuries, including but not limited to, injuries of or associated with the central

nervous and extrapyramidal motor systems, specifically tardive dyskinesia, which is a severe and often permanent neurological movement disorder.

30. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' dissemination of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential effects of exposure to and long term ingestion of Reglan/ metoclopramide to the medical community, Plaintiff, and other foreseeable users of the drug.

31. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain, suffering, psychological injury, and other injuries and damages due to the prescription and ingestion of Reglan/metoclopramide.

32. Recognizing the inadequate nature of the Defendants' Reglan/metoclopramide product labeling and warnings, in February 2009, the United States Food and Drug Administration (hereinafter referred to as "FDA") issued an advisory requiring the addition of a **Boxed Warning** for Reglan/metoclopramide. This new warning, which appears at the top of the label, spells out that "Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . ." Additionally, the new **Boxed Warning** now tells physicians and patients that "Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases . . . ."

33. In addition to requiring a Boxed Warning for Reglan/metoclopramide product labeling, the FDA required Reglan/metoclopramide manufacturers to implement

a Risk Evaluation and Mitigation Strategy ("REMS") because the FDA has determined that the use of Reglan/metoclopramide "pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide." This Medication Guide, setting out all the risks of the drug and to be given to all users "is necessary for the patients' safe use of Reglan (metoclopramide) . . . ." Unfortunately, neither this Boxed Warning nor the Medication Guide was available to Plaintiff at the time she was prescribed and ingested Reglan/metoclopramide.

Defendants' Wrongful Conduct

34. This case involves Defendants' failure to warn doctors and patients of information within their knowledge or possession which indicated that the subject Reglan/metoclopramide, when taken for long periods of time, caused serious, permanent and debilitating side effects, including tardive dyskinesia.

35. Defendants jointly and severally marketed, manufactured and distributed Reglan/metoclopramide, encouraged the long term use of these drugs, misrepresented the effectiveness of these drugs, and concealed the drugs' dangerous side effects.

36. Reglan/metoclopramide is indicated only as short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

37. Reglan/metoclopramide is indicated only for use for no greater than 12 weeks; however, Defendants represented that Reglan/metoclopramide was safe for use to treat nausea and/or esophageal reflux for durations that exceed 12 weeks.

38. Patients who use Reglan/metoclopramide for long periods of time are at a significantly increased risk of developing a severe and permanent neurological movement disorder.

39. Other serious side effects caused by ingesting Reglan/metoclopramide for long periods of time include, but are not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances, and interference with drug metabolism.

40. Patients who use Reglan/metoclopramide for long periods of time who are not able to effectively metabolize it are at a greater risk of developing these serious and permanent injuries.

41. Tardive dyskinesia, one of the serious side effects associated with the ingestion of Reglan/metoclopramide is a debilitating neurological disorder that often results in involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk, in addition to facial grimacing, uncontrollable tongue movements and other involuntary movements. Presently, there is no cure for tardive dyskinesia.

42. Plaintiff's diagnosed tardive dyskinesia, caused by the ingestion of metoclopramide, is permanent and disabling.

43. Wyeth is the successor-in-interest to A.H. Robins Company, Inc., which first obtained approval by the FDA to distribute metoclopramide, under the brand name "Reglan" under the FDA's New Drug Application (NDA)[1] schema in 1983.

44. Defendant Wyeth's predecessor in interest, A.H. Robins Company, Inc. expressly warranted to physicians that Reglan/metoclopramide is safe for long-term use.

45. A.H. Robins knew that its warranties regarding safety for long-term use would be relied upon by ordinary, reasonable, and prudent physicians who would share that information with other physicians in their communities and that eventually

[1] Upon information and belief, Wyeth was the holder of multiple NDAs for Reglan, metoclopramide and metoclopramide HCl.

physicians would come to rely on A.H. Robins' express warranties about Reglan/metoclopramide's safety for long-term use.

46. A.H. Robins' express warranties about the safety of Reglan/metoclopramide for long-term use were false and intentionally and negligently misleading.

47. As successor-in-interest to A.H. Robins Company, Inc., Wyeth is legally responsible for the conduct, fraudulent and negligent acts, intentional and willful omissions, and misleading representations and warranties made my A.H. Robins Company, Inc. concerning the safety and adequacy of Reglan/metoclopramide, and all liabilities stemming therefrom.

48. Wyeth manufactured, marketed and distributed Reglan, metoclopramide, and/or metoclopramide HCl through its Wyeth-Ayerst Laboratories Division in St. Davids, Pennsylvania and through its ownership of "ESI."[2]

49. Wyeth knew that it must fully disclose material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling, including warnings about risks and side effects, and test results involving animal studies, clinical studies, and the drug's bioavailability.

50. Wyeth knew that the data and information would be relied upon by the medical community, physicians, Plaintiff and other foreseeable users of Reglan/metoclopramide once the NDA was approved and Wyeth became the Reference Listed Drug Company for the drug.

[2] Upon information and belief, ESI was a former subsidiary which merged into Wyeth on or about December 15, 1998.

51. Wyeth intentionally and negligently disseminated misleading information to physicians across the county, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia.

52. Defendant Schwarz purchased from Wyeth the rights and *liabilities* associated with Reglan/metoclopramide, the terms of which, upon information and belief, obligated Schwarz to be responsible for claims related to the ingestion or use of Reglan/metoclopramide.

53. Defendant Schwarz entered into an indemnification agreement with Wyeth over the purchase of the innovator, Wyeth's Reglan®, which included disclosure of clinical studies on Reglan/metoclopramide that were not publicly available.[3]

54. Because Defendant Schwarz acquired Defendant Wyeth's Reglan/metoclopramide assets and liabilities while Wyeth was involved in ongoing litigation regarding Reglan/metoclopramide, and nevertheless agreed to indemnify Wyeth against all claims related to the ingestion of the drug, Schwarz knew or should have known that the NDA label for Reglan/metoclopramide (Wyeth's label) misrepresented the safety of the drug, withheld warnings of the known side effects of the drug, and knew or should have known of the safety issues surrounding it.

55. Under the FDA schema, Wyeth was the Reference Listed Drug Company (RLD), under a specific NDA, for Reglan/metoclopramide during time periods relevant to this case.

[3] Plaintiff does not have information regarding the maximum amount of liability under the defendants' indemnification agreement.

56. Under the FDA schema, Defendant Schwarz was the RLD and/or NDA Holder for Reglan/metoclopramide during time periods relevant to this case.

57. At all times material hereto, Defendants Wyeth and Schwarz, as the NDA Holder and/or RLD companies, were aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dyskinesia, visual disturbances, and interference with drug metabolism.

58. Defendants Wyeth and Schwarz have a duty to ensure their warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

59. Defendants Wyeth and Schwarz represented that Reglan/metoclopramide was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of Plaintiff.

60. Defendants Wyeth and Schwarz represented that Reglan/metoclopramide caused minimal side effects knowing that the drug caused central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented.

61. Defendants Wyeth and Schwarz had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long-term use that was not safe for patients.

62. Defendants Wyeth and Schwarz had actual knowledge, through their own studies and studies by independent investigators, that nearly one-third of all patients who

used Reglan/metoclopramide received it on doctors' prescriptions for 12 months or longer, rather than 12 weeks or less.

63. Defendants Wyeth and Schwarz also had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in package inserts and the PDR.

64. Defendants Wyeth and Schwarz knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize the drug, those patients have a greater risk of developing serious and permanent injuries.

65. Defendants Wyeth and Schwarz had actual knowledge of facts which demonstrated that representations in the Reglan/metoclopramide package insert, the PDR, and literature they distributed to physicians were false and misleading.

66. Defendants Wyeth and Schwarz failed to correct their monograph and/or disclose that knowledge to the medical community, Plaintiff, and other foreseeable users.

67. It is the public policy of the United States and the State of Missouri, as reflected in the Hatch-Waxman Act, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

68. Defendants Wyeth and Schwarz, as prescription drug manufacturers and/or distributors, knew or should have realized that so-called "drug product selection laws," enacted in every state, including the State of Missouri, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limitations, with a generic drug product that is therapeutically equivalent to the name brand drug product.

69. Defendants Wyeth and Schwarz knew or ought to have realized that generic drug manufacturers, including Defendant Pliva, customarily copy verbatim the package insert for the name brand prescription drug product to give the impression that the information contained in the package inserts accompanying their own generic prescription drugs is accurate and not misleading.

70. Defendants Wyeth and Schwarz knew or ought to have known that the generic drug manufacturers, including Defendant Pliva, also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

71. Defendants Wyeth and Schwarz knew or ought to have realized that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

72. Defendants Wyeth and Schwarz knew or should have known, specifically, that physicians would rely upon the information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand product, Reglan®, or generic Reglan/metoclopramide, and that many patients, in

accordance with those prescriptions, would be likely to ingest generic Reglan/metoclopramide.

73. Defendant Pliva, a generic drug manufacturer, submitted an Abbreviated New Drug Applications (ANDA) to the FDA, based on representations made by the RLD companies, requesting permission to manufacture, market, and distribute generic Reglan/metoclopramide.

74. Under the ANDA process, the Code of Federal Regulations *required* generic drug manufacturers such as Defendant Pliva, that were involved in the manufacture and distribution of generic metoclopramide and metoclopramide HCI, to submit labels for Reglan/metoclopramide that were identical in all material aspects to the reference listed drug label.

75. Under the Code of Federal Regulations, Pliva had a duty to ensure its Reglan/metoclopramide warnings to the medical community were accurate and adequate, to conduct post market safety surveillance, to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoclopramide.

76. Under the Code of Federal Regulations, if Pliva discovers information in the course of the fulfillment of its duties as outlined above, it must report that information to the medical community, Plaintiff, and other foreseeable users of Reglan/metoclopramide to ensure that its warnings are continually accurate and adequate.

77. Defendant Pliva failed to investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug labels.

78. Defendant Pliva failed to review the available medical literature applicable to the metoclopramide drug and/or metoclopramide HCl drug.

79. Defendant Pliva relied entirely upon the name brand manufacturer and the referenced listed drug companies to review the aforementioned medical literature for Reglan/metoclopramide.

80. Under the FDA schema, if the FDA approves a label change as requested by an ANDA holder, such as Defendant Pliva, the NDA holder (also referred to as the RLD company) must also amend its label accordingly.

81. Defendants, including Defendant Pliva, failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide.

82. Defendants disseminated to physicians, through package inserts, the publication of the PDR, and otherwise, information concerning the properties and effects of Reglan/metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

83. Defendants knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long-term side effects of ingesting the drug.

84. Defendants failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short-term and long-term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

85. Defendants owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/metoclopramide, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

86. Reglan/metoclopramide was widely advertised by Defendants as a safe and effective treatment of diabetic gastroparesis, gastroesophageal reflux disease ("GERD"), and other gastrointestinal disorders.

87. Defendants failed to conduct and report post market safety surveillance on Reglan/metoclopramide.

88. Defendants failed to review all adverse drug event information[4] and to report any information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan/metoclopramide.

89. Defendants failed to monitor all relevant scientific literature related to Reglan/metoclopramide.

90. Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/metoclopramide for long periods of time.

91. Defendants failed to report data, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Reglan/metoclopramide.

[4] Defendants are required to review all adverse drug experience information obtained or otherwise received . . . from any source . . . including derived from postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports from the scientific literature, and unpublished scientific reports. 21 C.F.R. § 317.80(b).

92. Defendants knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to tardive dyskinesia and other extrapyramidal side effects, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than 12 weeks "cannot be recommended."

93. Defendants concealed the fact that earlier false information disseminated by A.H. Robins Company and/or Wyeth representing long-term Reglan/metoclopramide therapy to be reasonably safe, was unscientific and false.

94. Defendants concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other extrapyramidal side effects with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs and that epidemiological studies have consistently confirmed this expectation.

95. Defendants also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders with Reglan/metoclopramide for longer than 12 weeks is unlikely to be reasonably safe.

96. Some or all of the Defendants, as a result of their participation as Defendants in previous and ongoing litigation concerning Reglan/metoclopramide products, received clear notice of Wyeth's suppression of important safety information concerning Reglan/metoclopramide yet, despite this notice, chose to ignore the information and join consciously in the suppression.

COUNT I
(Strict Products Liability – Design Defect)

97. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

98. At all times relevant hereto, Defendants were engaged in the business of designing, researching, manufacturing, testing, marketing, selling, distributing, supplying and/or placing into the stream of commerce the prescription drugs Reglan/metoclopramide.

99. The Reglan/metoclopramide designed, manufactured, marketed, sold, distributed, supplied, and/or placed into the stream of commerce by Defendants was defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation and other drugs performed the same function without the increased risk of Reglan/metoclopramide.

100. The foreseeable risks associated with the design or formulation of Reglan/metoclopramide include, but are not limited to, the fact that the design or formulation of Reglan/metoclopramide is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

101. The Reglan/metoclopramide ingested by Plaintiff was expected to reach her without substantial change in the condition in which it was sold.

102. The Reglan/metoclopramide ingested by Plaintiff reached her without substantial change in the condition in which it was sold.

103. Plaintiff was a person who would reasonably be expected to use Reglan/metoclopramide.

104. As a direct and proximate result of the design defects in the Reglan/metoclopramide ingested by Plaintiff, she has sustained and will continue to sustain severe physical injuries, emotional distress, and economic losses and consequential damages, and is therefore entitled to compensatory relief according to proof.

COUNT II
(Strict Products Liability – Failure to Warn)

105. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

106. At all times relevant hereto, Defendants were engaged in the business of designing, researching, manufacturing, testing, marketing, selling, distributing, supplying and/or placing into the stream of commerce the prescription drugs Reglan/metoclopramide.

107. Defendants owed a duty of care to adequately warn Plaintiff and her health care providers of the risks associated with the use of Reglan/metoclopramide.

108. The Reglan/metoclopramide designed, manufactured, marketed, sold, distributed, supplied, and/or placed into the stream of commerce by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

109. By failing to warn Plaintiff and her health care providers of significant risks of serious bodily harm associated with the use of Reglan/metoclopramide, Defendants breached their duty to Plaintiff of reasonable care and safety.

110. The Reglan/metoclopramide used by Plaintiff was prescribed and used in a manner reasonably anticipated by Defendants.

111. As a direct and proximate result of the inadequate warnings associated with the Reglan/metoclopramide used by Plaintiff, she has sustained and will continue to sustain severe physical injuries, emotional distress, and economic losses and consequential damages, and is therefore entitled to compensatory relief according to proof.

COUNT III
(Negligence)

112. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

113. Defendants had a duty to Plaintiff to exercise reasonable care in the design, research, manufacture, testing, sale, marketing, distribution, supply, and/or placement of Reglan/metoclopramide into the stream of commerce, including a duty to ensure that its product did not pose a significantly increased risk of bodily harm and adverse events.

114. Defendants failed to exercise ordinary care in the design, research, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, supply, and distribution of Reglan/metoclopramide into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm and was not safe for usage by consumers, including Plaintiff.

115. Defendants, and each of them, breached their duty to Plaintiff and were negligent in their actions, misrepresentations, and omissions toward Plaintiff, in that, Defendants:

(a) Failed to use due care in developing, testing, designing and manufacturing Reglan/metoclopramide so as to avoid the aforementioned risks to individuals when Reglan/metoclopramide was being used for treatment of patients;

(b) Failed to accompany their product with proper or adequate warnings regarding adverse side effects and health risks associated with the use of Reglan/metoclopramide and the comparative severity and duration of such adverse effects;

(c) Failed to accompany their product with proper or adequate rate of incidence or prevalence of permanent irreversible neurological damage;

(d) Failed to provide warnings that accurately reflected the symptoms, scope, or severity of the side effects and health risks;

(e) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Reglan/metoclopramide;

(f) Failed to provide adequate training or information to medical care providers for appropriate use of Reglan/metoclopramide;

(g) Failed to adequately warn consumers and medical prescribers (but instead actively encouraged the sale of Reglan/metoclopramide), about the following: (1) that Reglan/metoclopramide should not be prescribed for more than twelve weeks; (2) that Reglan/metoclopramide can cause neuromuscular side effects, including, but not limited to, tardive dyskinesia; (3) that Reglan/metoclopramide should be discontinued in the face of involuntary facial, tongue, jaw, limb or trunk movements; and (4)

that the health risks posed by Reglan/metoclopramide may become debilitating, difficult, and painful, necessitating lengthy and/or repeated visits to the doctor, clinic, or hospital;

(h) Failed to adequately test and/or warn about the use of Reglan/metoclopramide, including, without limitation, the possible adverse side effects and health risks caused by the use of Reglan/metoclopramide;

(i) Failed to adequately warn users, consumers and physicians about the severity, scope, and likelihood of neurological damage and related dangerous conditions to individuals taking Reglan/metoclopramide; and

(j) Representing to physicians, including but not limited to Plaintiff's prescribing physician, that Reglan/metoclopramide was safe and effective for use.

116. Despite the fact that the Defendants knew or should have known that Reglan/metoclopramide posed a serious risk of bodily harm of which Plaintiff and the general public would not be aware, Defendants continued to manufacture and market Reglan/metoclopramide for usage in patients such as Plaintiff.

117. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care.

118. The Reglan/metoclopramide ingested by Plaintiff was expected to reach her without substantial change in the condition in which it was sold.

119. The Reglan/metoclopramide ingested by Plaintiff reached her without substantial change in the condition in which it was sold.

120. The capability of Reglan/metoclopramide to cause serious personal injuries and damages such as those suffered by Plaintiff was not the result of any voluntary action or contributory negligence of Plaintiff.

121. The Reglan/metoclopramide at issue in this suit was consumed by Plaintiff as directed and without change in its form or substance.

122. The negligent acts and/or omissions of Defendants, as set forth above, constitute an entire want of care so as to indicate that the acts and/or omissions in question were the result of conscious disregard, indifference, and/or malice so as to give rise to an award of punitive damages.

123. As a direct and proximate result of Defendants' carelessness and negligence as set forth herein, Plaintiff has sustained and will continue to sustain severe physical injuries, emotional distress, and economic losses and consequential damages, and is therefore entitled to compensatory relief according to proof.

COUNT IV
(Breach of Express Warranty)

124. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

125. Defendants expressly warranted that Reglan/metoclopramide was a safe and effective drug for treatment of gastroesophageal reflux disease ("GERD").

126. The Reglan/metoclopramide manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers, such as Plaintiff, when used as intended.

127. The Reglan/metoclopramide administered to Plaintiff was expected to, and did reach her without a substantial change in its condition.

128. Defendants, through their advertising, product labeling, promotional materials, expressly warranted that Reglan/metoclopramide was safe and effective for the use for which it was intended.

129. Defendants breached express warranties in that Reglan/metoclopramide was unsafe in light of the increased risk of serious injury when used by patients, such as Plaintiff.

130. Plaintiff relied to her detriment on Defendants' express warranties.

131. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has sustained and will continue to sustain severe physical injuries, emotional distress, and economic losses and consequential damages, and is therefore entitled to compensatory relief according to proof.

COUNT V
(Breach of Implied Warranty)

132. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

133. At the time Defendants designed, manufactured, sold, marketed, and distributed Reglan/metoclopramide, Defendants knew of the use for which Reglan/metoclopramide was intended and impliedly warranted that it was of merchantable quality and fit and safe for ordinary use.

134. Plaintiff and her healthcare providers reasonably relied upon the skill and judgment of Defendants as to whether Reglan/metoclopramide was of merchantable

quality and fit and safe for its intended use and upon Defendants' implied warranty as to such matters.

135. Contrary to the implied warranty, Reglan/metoclopramide was not of merchantable quality or fit and safe for its intended use because it was unreasonably dangerous as described herein.

136. Plaintiff reasonably relied to her detriment on the Defendants' implied warranties.

137. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has sustained and will continue to sustain severe physical injuries, emotional distress, and economic losses and consequential damages, and is therefore entitled to compensatory relief according to proof.

COUNT IV
(Violation of Missouri Merchandising Practices Act)

138. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

139. Defendants, by and through their agents, servants and employees, employed deception, fraud, false pretense, false promise, misrepresentation, unfair practice, and the concealment, suppression, and omission of material facts in connection with the sale or advertisement of Reglan/metoclopramide in violation of the Missouri Merchandising Practices Act ("MMPA"), RSMo §407.020 and §407.025.

140. Defendants' offer for sale of a consumer product, Reglan/metoclopramide, in trade or commerce, constitutes a representation that the product, Reglan/metoclopramide is reasonably safe for its intended purpose.

141. Defendants' offer for sale of a consumer product, Reglan/metoclopramide,

in trade or commerce, constitutes a representation that the product, Reglan/metoclopramide is reasonably safe for its intended use.

142. Defendants have engaged in deceptive acts or practices in violation of the MMPA including, but not limited to, the following: (1) knowingly, intentionally, and/or recklessly omitting, concealing, and/or suppressing their own data from investigations and clinical trials, other analyses, studies, tests, understandings, and conclusions about the true efficacy of Reglan/metoclopramide; (2) knowingly, intentionally, and/or recklessly omitting, concealing, and/or suppressing their own data from investigations and clinical trials, other analyses, studies, tests, understandings, and conclusions about the safety of Reglan/metoclopramide; (3) knowingly, intentionally, recklessly omitting, suppressing, and/or concealing the unreasonably dangerous nature of Reglan/metoclopramide; and (4) knowingly, intentionally, recklessly omitting, suppressing, and/or concealing the fact that use of Reglan/metoclopramide posed a significant increased risk of extrapyramidal side effects, including tardive dyskinesia, especially when Reglan/metoclopramide is used for a period of time exceeding twelve weeks.

143. Defendants have violated the MMPA by consciously omitting, concealing, suppressing, and/or or otherwise failing to communicate and notify the medical community, Plaintiff, and other consumers of Reglan/metoclopramide, of the negative safety information they possessed.

144. The negative efficacy and/or safety information associated with Reglan/metoclopramide was a material fact in that Plaintiff would not have purchased Reglan/metoclopramide, and would not have sustained injury from using

Reglan/metoclopramide, if Defendants had not omitted, suppressed, concealed, and/or otherwise failed to disclose the negative efficacy and safety information associated with Reglan/metoclopramide.

145. Defendants intended that Plaintiff rely upon these suppressions, concealments, and/or omissions as to the efficacy, description, quality, safety, and/or characteristics of Reglan/metoclopramide. Defendants deceptive acts and/or practices were specifically designed and intended to induce the Plaintiff to buy Reglan/metoclopramide and the deception occurred during a course of conduct involving trade or commerce.

146. As a direct and proximate result of the above violations of the MMPA, Plaintiff was actually deceived and such deception caused the Plaintiff to suffer personal physical injury and actual damages from expending consideration and value, i.e. money, for the purchase of the ineffective, unsafe, and/or unreasonably dangerous drug: Reglan/metoclopramide.

147. Plaintiff purchased Reglan/metoclopramide manufactured, marketed, promoted, and sold by Defendants, and suffered personal physical injury and an ascertainable loss of money, as a result of Defendants use or employment of methods, acts, or practices declared unlawful by the MMPA and brings this action to recover monetary damages in the amount sufficient to make her whole.

COUNT V
(Misrepresentation and Fraud – As to Defendants Pfizer, Wyeth, and Schwarz)

148. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

149. As innovators and/or reference listed drug holders ("RLDs") of the drug

Reglan®, and given their vast experience as drug product manufacturers, defendants Wyeth and its predecessors, and Schwarz were aware their drug product would be the forerunner to generics metoclopramide and metoclopramide HCI.

150. Given the foreseeable advent of generic versions of the drug they created, defendants Wyeth and its predecessors, and Schwarz, had a duty to all foreseeable consumers of the research conducted (whether data was released or not), labeling language, the monograph submitted to the Physician's Desk Reference, and data submitted to the FDA. Foreseeable consumers of this material would clearly include prescribing physicians and persons who would be dispensed and subsequently ingest metoclopramide and metoclopramide HCI.

151. Thus, defendants Wyeth and its predecessors, and Schwarz, had a clear duty to dispensers and consumers of generic forms of Reglan to warn of foreseeable risk and harm.

152. Defendants Wyeth and its predecessors, and Schwarz, through their advertising, labeling, marketing, and sales/detail persons, made significant representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Plaintiff rely on such material representations and in doing so, and as set forth in the above paragraphs, violated the MMPA, RSMo §407.020 and §407.025; Plaintiff acted in actual and justifiable reliance on such material misrepresentations and was injured as a result.

153. In addition, and in the alternative if necessary, defendants Wyeth, and its predecessors, and Schwarz knowingly omitted and downplayed material information,

which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff rely on defendants' misrepresentations; Plaintiff acted in actual and justifiable reliance on said Defendants' representations and was injured as a result.

154. Defendants Wyeth and its predecessors, and Schwarz, committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Reglan/metoclopramide at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

155. Defendants Wyeth and its predecessors, and Schwarz, misrepresented to the FDA, Plaintiff, and the health care industry the safety and effectiveness of Reglan/metoclopramide and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Reglan/metoclopramide.

156. Defendants Wyeth and its predecessors, and Schwarz, made these misrepresentations and actively concealed adverse information at a time when they knew, or should have known, that Reglan/metoclopramide had defects, dangers, and characteristics that were other than what they had represented to Plaintiff and the health care industry generally. Specifically, said Defendants misrepresented to and/or actively concealed from Plaintiff and the consuming public that:

(a) Reglan/metoclopramide had statistically significant increases in neuromuscular side effects which could result in serious injury;

(b) Patients on Reglan/metoclopramide should not take it more than twelve weeks; and

(c) Reglan/metoclopramide was not fully and adequately tested for the neuromuscular side effects.

157. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of defendants Wyeth and its predecessors, and Schwarz, Plaintiff suffered significant and ongoing injuries and damages. Further, because said Defendants' conduct was willful, reckless, intentional and/or maliciously fraudulent, Plaintiff is entitled to an award of exemplary damages.

DAMAGES

158. As a direct and proximate result of the above-described acts and omissions of Defendants, Plaintiff Shirley Brinkley has incurred actual damages in excess of $75,000.00, including but not limited to the following:

(a) Reasonable and necessary medical expenses incurred in the past;

(b) Reasonable and necessary medical expenses reasonably likely to be incurred in the future;

(c) Conscious physical pain and suffering experienced in the past;

(d) Conscious physical pain and suffering reasonably likely to be experienced in the future;

(e) Mental anguish in the past;

(f) Mental anguish likely to be experienced in the future;

(g) Physical disfigurement in the past;

(h) Physical disfigurement likely to be experienced in the future;

(i) Physical impairment in the past;

(j) Physical impairment likely to be experienced in the future;

(k) Pre and post-judgment interest at the lawful rate;

(l) Exemplary or punitive damages; and

(m) Such other applicable damages as the Court deems appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Shirley Brinkley prays for judgment against Defendants Pfizer, Inc., Wyeth, LLC f/k/a Wyeth, Inc., Schwarz Pharma, Inc., and Pliva, Inc. f/k/a Sidmak Laboratories, Inc., as follows:

(a) For compensatory damages as alleged, jointly and/or severally against Defendants, in excess of the jurisdictional minimum;

(b) For exemplary or punitive damages alleged against Defendants;

(c) Costs of court and reasonable attorney fees necessary for preparation of this case for trial;

(d) Prejudgment interest at the highest rate allowed by law;

(e) Interest on the judgment at the highest legal rate from the date of judgment until collected; and

(f) All such other and further relief at law and in equity to which Plaintiff may show herself to be justly entitled.

JURY DEMAND

Plaintiff hereby demands a trial by jury in this case as to such issues so triable.

Respectfully submitted,

BERTRAM & GRAF, L.L.C.

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